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Food and Drug Administration  
Florida District  
555 Winderley Place  
Suite 200  
Maitland, Florida 32751

Telephone: 407-475-4700  
FAX: 407-475-4769

**VIA CERTIFIED MAIL**

**WARNING LETTER**

FLA-01-58

May 15, 2001

Diego J. Garcia, President and Owner  
DJ Tuna Express  
P.O. Box 12758  
Hialeah, FL 33012-1620

Dear Mr. Garcia:

We inspected your firm, located at 2265 W. 9<sup>th</sup> Avenue, Unit #2, Hialeah, FL on March 20-21, 2001 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your fresh fish to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. You can find this Act and the seafood HACCP regulations through links in FDA's home page at [www.fda.gov](http://www.fda.gov).

The deviations were as follows:

You must implement the record keeping system listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations for the presence of ice twice daily at the Finished Product Storage critical control point to control the histamine formation hazard listed in your HACCP plan for scombroid species.

You must maintain sanitation control records to document the monitoring and correction of sanitation conditions and practices during processing to comply with 21 CFR 123.11(c). However, no such sanitation control records were maintained.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation, such as completed process monitoring and sanitation control records or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for the delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Jimmy E. Walthall, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Mr. Walthall at (407) 475-4731.

Sincerely,



*for*

Emma R. Singleton,  
Director, Florida District